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Implementation of Modified Constraint-Induced Therapy in Upper Limb Stroke Rehabilitation in an Inpatient Rehabilitation Hospital

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Section 1: Introduction

Stroke is a leading cause of adult disability in the United States, with an estimated 7 million stroke survivors (Wolf & Nilsen, 2015). With an annual incidence of approximately 795,000 new or recurrent strokes in the United States, this is one of the most significant physical disabilities treated by occupational therapy practitioners (Go et al., 2013; Nilsen et al., 2015). Stroke survivors face multiple challenges, such as weakness on one side of the body, decline in cognitive and emotional functioning, social disability, inability to walk and care for themselves, and a decrease in community participation (Wolf & Nilsen, 2015). Broeks, Lankhorst, Rumping, & Prevo (1999) state that about half of stroke survivors will be left with a non-functioning arm as a result of paralysis, with most of the motor recovery occurring within the first three months. Taub, Crago, and Uswatte (1998) have postulated that stoke survivors with unilateral upper extremity weakness may preferentially use the non-affected side while avoiding the use of the affected side, resulting in a "learned nonuse" phenomenon, first observed in animal experiments with monkeys (p. 55). Constraint-induced therapy (CIT) was proposed by Taub and his colleagues (1998) to overcome learned non-use by restraining the use of the non-affected arm, while engaging the patient in functional activities with the affected arm, thus inducing cortical reorganization based on a theory of brain plasticity (Miltner, Bauder, Sommer, Dettmers, & Taub, 1999; Shi, Tian, Yang, & Zhao, 2001; Page, Sisto, Levine, Johnston, & Hughes, 2001). CIT involves restraint of the unaffected limb for up to 90% of waking hours, forcing use of the affected limb during daily activities (Taub, Crago, & Uswatte, 1998; Wolf & Nilsen, 2015). CIT protocol also includes intensive and repetitive training in functional task activities by shaping or task practice using the affected limb for 6 hours each day for 2 weeks (Morris, Taub, & Mark, 2006, Wolf and Nilsen, 2015). Modified constraint-induced movement therapy (mCIT) is a shortened version of the original CIT protocol described by Taub, Crago, and Uswatte (1998) in which the amount of time that restraint is applied to the less affected limb is decreased and / or distributed over a longer period of time (Page, Sisto, Levine, Johnston, & Hughes, 2001). There are several reports of the efficacy of CIT in upper extremity stroke rehabilitation (Miltner et al., 1999; Taub, et al., 2006; Wolf et al., 2006). Several studies including that of Page, Sisto, Levine & McGrath (2004) have shown that modified constraint induced therapy (mCIT) is an efficacious method of improving function and use of the affected arm of patients with hemiparesis following chronic stroke. The efficacy of mCIT in increasing affected arm use and function has been demonstrated mostly in the outpatient clinics on subacute and chronic stroke patients (Page, Sisto, Johnson, Levine, & Hughes, 2002; Shi, Tian, Yang, &, Zhao, 2011; Page, Sisto, Levine & McGrath, 2004). There are reports of preliminary and pilot studies demonstrating the feasibility and efficacy of mCIT in the rehabilitation of patients with acute stroke (Dromerick, Edward, and Hahn, 2000; Page, Levine, & Leonard, 2005).

Problem Statement

In order to realize the goal of the centennial vision of the American Occupational Therapy Association (AOTA, 2007), there is need for occupational therapy practice in stroke rehabilitation to be based on the best available evidence (Gillen, 2015). Reviews have uncovered strong evidence of effective occupational therapy interventions for patients recovering from stroke especially those addressing motor deficits (Gillen, 2015; Nilsen et al., 2015). Despite the convergence of evidence, there is a disconnect between what has been learnt from evidence and the real world of occupational therapy practice, a gap that seems to be widening according to Gillen (2015). Among the multiple factors contributing to this gap is the attachment of many occupational therapists to traditional approaches even with limited evidence of their effectiveness (Gillen, 2015). The review by Nilsen et al. (2015) described common elements in effective interventions for motor rehabilitation following stroke to include emphasis on "training of the impaired arm and hand using goal-directed, individualized tasks that promote frequent repetitions of task-related or task-specific movements" (p4-p5). These elements are central to CIT and mCIT and are consistent with occupational therapy philosophy of occupation-based practice (AOTA, 2014). However, Latham et al. (2006) noted in a study of rehabilitation techniques for clients with strokes in six rehabilitation hospitals that CIT was the approach or type of intervention used in only 2.7% of all interventions.

Based on the opinions of therapists in Southwestern Ohio, Daniel, Howard, Braun and Page (2012) explained the low rate of application of CIT in clinical practice to include concern about payer reimbursement for these interventions, the potential difficulty the patients would face during the clinical therapy sessions, the prolonged duration of restrictive devise application, and the lack of awareness of the availability of modifications in CIT that addressed these challenges. Page, Sisto, Levine, Johnston, and Hughes (2001) described a modified constraint-induced therapy (mCIT) protocol to address these limitations on the original CIT by distributing shorter treatment sessions to 30 minutes, limiting the restriction of the less affected upper extremity to 5 hours per day for 5 days per week, and extending the protocol to 10 weeks of outpatient treatment. These researchers demonstrated the feasibility and efficacy of mCIT in chronic strokes (Page, Sisto, Levine, & McGrath, 2004), subacute strokes (Page, Sisto, Johnston, Levine, & Hughes 2002), and acute strokes (Page, Levine, & Leonard, 2005). The feasibility and efficacy of mCIT protocols lasting from 2-4 weeks in subacute, and acute strokes have been demonstrated in studies from China, Europe, and India, and the United States (Wang, Zhao, Zhu, Li, & Meng, 2011; El-Helow et al., 2015; Singh & Pradhan, 2013; Dromerick et al., 2009; Dromerick, Edward, and Hahn, 2000; Page, Levine, and Leonard, 2005). Occupational therapists need to bridge the evidence-practice gap by implementing intervention strategies that are based on scientific evidence, and are proven to be effective in addressing occupational performance deficits in stroke patients with motor impairments. Since available evidence have clearly demonstrated the efficacy and feasibility of modified constraint-induced therapy (mCIT) in chronic, subacute, and acute stroke, it makes sense to explore its implementation in routine stroke rehabilitation in an inpatient rehabilitation hospital, which is the routine setting for most acute stroke patients. Since mCIT has been demonstrated to reverse the effects of learned nonuse (Page et al, 2005), it does make more sense to apply it early in the acute setting in the first instance to prevent patients from learned nonuse.

Purpose Statement

To implement an evidence-based approach – modified constraint-induced therapy (mCIT) in the upper extremity rehabilitation of patients with acute stroke with hemiparetic upper extremity admitted to an inpatient rehabilitation, by demonstrating its feasibility and efficacy in increasing the motor recovery of the affected extremity, and increasing the number and quality of arm use compared to the traditional occupational therapy intervention.

Project Objectives

This research proposal is an experimental study to test the hypothesis that the implementation of modified constraint-induced therapy (mCIT) for upper extremity rehabilitation of patients with acute stroke in an inpatient rehabilitation hospital will lead to greater motor recovery of the affected extremity, and an increase in number and quality of arm use, compared to traditional occupational therapy interventions.

Theoretical Framework

Developments in neuroscience and movement science provided evidence of a new approach to rehabilitation called constraint-induced therapy (CIT) described by Taub, Crago, and Uswatte (1998) based on observations in animal experiments and successfully adapted to clinical use. Constraint-induced therapy (CIT) is based on a principle in which operant-conditioning techniques are applied to change the behavior of subjects with stroke from developing learned-nonuse, resulting in increased use of the affected upper limb in daily activities (Taub, Crago, & Uswatte, 1998; Page, Johnson, Levine, & McGrath, 2004). The important distinction with CIT is that rather than using compensatory strategies as in the traditional approaches to stroke rehabilitation, CIT restricts the less affected upper extremity while applying intensive training of the affected upper extremity with "shaping" and task practice based on operant conditioning for 6 hours daily for 14 days (Taub, Crago, & Uswatte, 1998, p. 158). The restraint and shaping techniques used work to overcome "learned-nonuse" following stroke (Taub, Crago, & Uswatte, 1998, p.155). CIT causes its effect as a result of the induction of cortical reorganization based on a theory of brain plasticity (Miltner, Bauder, Sommer, Dettmers, & Taub, 1999; Taub et al., 1998). A more detailed description of the theoretical framework is provided in the literature review.

Significance of the study

The focus of occupational therapy is to help individuals achieve health, wellbeing, and participation in life through engagement in occupations (i.e., activities) AOTA, 2014). In inpatient rehabilitation hospitals, occupational therapists achieve these through evaluation and assessment of clients to know the extent of deficits after stroke, to determine the needs and goals of the clients (Wolf & Nilsen, 2015). In inpatient rehabilitation hospitals, upper extremity stroke rehabilitation by occupational therapists typically includes a combination of approaches. The approaches are broadly speaking in two categories namely, a skills remediation or bottom-up approach, and an occupation-based or top-down approach (Coster, 1998; Gray, 1998; Trombly, 1993). The skills remediation approach addresses the motor or sensory deficits with ultimate goal of improving the general body function (Coster, 1998; Gray, 1998; Trombly, 1993). The occupation-based or top down approach includes an assessment of the extent the individual is able to participate in daily occupations to the extent that meets the client's personal goals and fulfill his/her roles and society's expectations Coster, 1998; Fisher, 1998; Gray, 1998). On the basis of this assessment, the therapist then identifies and addresses the critical tasks that may be responsible for impaired occupational performance, and the "specific aspects of task performance, or activities, that are most limiting the person's engagement" (Coster, 1998, p. 340).

According to Smallfield and Karges (2009), occupational therapy interventions in inpatient rehabilitation hospitals include prefunctional activities in 65.77% of the sessions. These are "impairment-focused-activities" aimed at improving the body function and structure of the client to prepare them for functional activities (Smallfield & Karges, 2009, p. 411). These include range of motion exercises, and those classified by Latham et al. (2006) as upper extremity control activities, defined as the training and facilitation of normal movement, strength, range of movement, or alignment in the upper extremity. In addition, traditional inpatient rehabilitation stroke programs also focus on functional activities, predominantly activities of daily living (ADLs), including dressing activities, grooming, eating and toileting, and less so on instrumental activities of daily living (IADLs), bed mobility, and wheelchair training. In the inpatient rehabilitation facility where this study will be conducted, functional activities, predominantly ADLs, neuromuscular interventions like balance training, strengthening, and postural awareness are the most common types of interventions used across most activities (personal observation).

Based on the conclusion of reviews by Ernst (1990), there was no convincing evidence at that time, of the effectiveness of rehabilitation of any kind on functional status of stroke survivors, thus making the case for well-designed trials to determine effective interventions. According to Taub, Crago, and Uswatte (1998), this gap in evidence from clinical research to support the efficacy of interventions used in stroke rehabilitation began to be filled by advances neuroscience and behavioral psychology, and subsequent emergence of CIT.

In a survey of 92 therapists in southwestern Ohio, Daniel, Braun and Page (2012) found that 83% of therapists working in outpatient and inpatient hospital and neuro-rehabilitation settings felt that most clinics would not have the resources to implement CIT, and 75% reported that it would be difficult or very difficult to administer CIT in their clinics. Other potential obstacles mentioned by majority of therapists included concern about payer reimbursement for CIT, and potential difficulty the patients would face during the clinical therapy sessions and the prolonged duration of restrictive devise applications. Page, Sisto, Levine, Johnston, and Hughes (2001) designed a modification of CIT to address these limitations on the CIT by distributing shorter treatment sessions to 30 minutes, limiting the restriction of the less affected upper extremity to 5 days per week for 5 hours, and extending the protocol to 10 weeks of outpatient treatment (Page, Sisto, Levine, Johnston, & Hughes, 2001). Studies on modified constraint-induced therapy (mCIT) demonstrated increased use and function in the affected upper extremity after mCIT participation by patients in chronic stroke (Page, Levine, & Leonard, 2005; Page, Levine, Leonard, Szaflarski, & Kissela, 2008; Page, Sisto, Levine, & McGrath, 2004), the and increase in upper extremity ability continued up to three months after intervention in the study.

Modified constraint-induced therapy (mCIT) was initially described as outpatient stroke rehabilitation intervention for patients chronic strokes. Page, Levine and Leonard (2005) reported modest improvement in limb use and function in a randomized controlled pilot study to determine the feasibility of mCIT in acute stroke compared to traditional rehabilitation in acute stroke patients with upper limb hemiparesis. These results are suggestive of use-dependent cortical reorganization resulting in functional improvement, and offer great potentials for recovery since as noted by Page et al (2005), acute and subacute phases are “believed to be times of considerable potential recovery” (p. 31). However, this was an outpatient modified protocol combining the ½ hour 3 day/week therapy on the affected upper extremity and the 5 hour 5 day/week restriction of the unaffected arm performed in the participant’s home for a 10 week study duration. More studies have been published in recent years demonstrating the efficacy of mCIT for inpatient rehabilitation in acute and subacute strokes with protocols lasting from 2-4 weeks in studies in China, Europe, and India, and the United States (Wang, Zhao, Zhu, Li, & Meng, 2011; El-Helow et al., 2015; Singh & Pradhan, 2013; Dromerick et al., 2009; Dromerick, Edward, and Hahn, 2000; Page, Levine, and Leonard, 2005). Nijland, Wegen, Krogt, Bakker, Buma, Klomp, Kordelaar, and Kwakkei, 2013 have described in detail a protocol for early mCIT in acute stroke.

Since the 1900s, when researchers like Taub, Crago, & Uswatte (1998) noted the paucity in evidence of the effectiveness of credible interventions on outcomes following rehabilitation, the last 3 decades have witnessed “ almost 1000 randomized control trials in stroke rehabilitation,” with “ very little translation of this evidence base into clinical practice (Stinear, Ackerley, & Byblow, 2013, p. 2039). Stinear et al. (2013) noted that the evidence base for new motor rehabilitation techniques like mCIT initiated early after stroke was relatively small as very few of the good quality studies are initiated during the time when most rehabilitation occurs. Thus majority of the evidence base in CIT and mCIT were obtained in patients with chronic stroke, whereas stroke rehabilitation typically begins in the acute phase in inpatient rehabilitation hospitals (Stinear et al., 2013; Wolf & Nilsen, 2015). This may likely explain the paucity in implementation of mCIT in routine clinical practice even when reasonably strong evidence of its efficacy has emerged. Latham and colleagues (2006)' s data demonstrated that CIT was the approach or type of intervention used in 2.7% of all interventions in a study of rehabilitation techniques for clients with strokes in six rehabilitation hospitals. The most frequently used activities included upper extremity control (22.9% of total treatment time), dressing activities (14.9 % of total treatment time), and pre-functional activities (9% of total treatment time), whereas CIT was the approach used in 1.8-4.1% of all treatment sessions in inpatient rehabilitation hospitals (Latham et al., 2006). In contrast, the more common neuromuscular interventions were balance training, (44.5%), postural awareness (44.7%), and motor learning (42.6%), musculo-skeletal interventions like strengthening (31.5%), and passive range of motion (19.4%), compared to the 2.7% of all interventions that were based on CIT.

Summary

This study will therefore seek to demonstrate the efficacy of mCIT in upper extremity rehabilitation of patients with acute stroke resulting in hemiplegia in an inpatient rehabilitation hospital as a way to demonstrate its feasibility and applicability in this setting for this subset of stroke patients. It is expected that the study will provide a model for the implementation and application of mCIT in stroke rehabilitation in inpatient rehabilitation hospitals and serve as a pilot program for an evidence-based approach to rehabilitation of patients with acute stroke in inpatient rehabilitation hospitals. Stinear et al. (2013) argue that testing new treatment for stroke rehabilitation in the time and place of its intended use "paves the way for its translation to clinical practice" (p. 2041). Nijland et al (2013) refer to studies that suggest a critical time window of reactive neuroplasticity within the first 30 days after stroke as an opportunity for therapists to "successfully apply evidence-based therapies such as mCIT for acute stroke survivors" (p. 6). This study will achieve the aim of translating research evidence to clinical practice in the quest to realize the Centennial Vision of occupational therapy as a "powerful, widely recognized, science-driven, and evidence-based profession" (American Occupational Therapy Association, 2007).

Section 2: Literature Review

Introduction

Strokes commonly result in motor impairments that may impair a person's ability to engage in meaningful occupations (Nilsen et al., 2015). Occupational therapists provide rehabilitation to assist stroke survivors to improve their occupational performance using a variety of approaches across all settings. With an annual incidence of approximately 795,000 new or recurrent strokes in the United States, this is one of the most significant physical disabilities treated by occupational therapy practitioners (Go et al., 2013, Nilsen et al., 2015). Among 108 stroke survivors in the Framingham Heart Study of the National Heart, Lung, and Blood Institute, 50% had hemiparesis, 30% were unable to walk without assistance, and 25% were dependent in activities of daily living (Kelly-Hayes et al., 2003). Stroke patients may receive care in acute care settings, inpatient rehabilitation hospitals, outpatient rehabilitation centers, home, and/or community settings. After receiving care in the acute care phase in the period immediately after the onset of the stroke, usually in a specialized stroke unit or neurological intensive care unit, survivors who have continued rehabilitation needs that are beyond the capacity of community-based programs are usually admitted to an inpatient rehabilitation hospital (Management of Stroke Rehabilitation Working Group, 2010; Wolf and Gillen, 2015). Broeks, Lankhorst, Rumping and Prevo (1999) state that about half of stroke survivors will be left with functional impairment of the upper extremity as a result of paralysis, with most of the motor recovery occurring within the first three months. There is need for occupational therapists to develop and implement evidence-based approaches to address motor impairments that affect the occupational performance of stroke patients and their independence in ADLs and instrumental activities of daily living. In their critical appraisal of research in this topic, Nilsen and colleagues (2015) found evidence of a variety of interventions that can improve the occupational performance of stroke survivors with motor impairment.

While concerns were raised by researchers like Ernst (1990) in the 1990s, of the paucity in convincing evidence of the effectiveness of rehabilitation of any kind on functional status of stroke survivors, there were significant developments in neuroscience and movement science providing evidence of a new approach to rehabilitation called constraint-induced therapy (CIT) described by Taub, Crago, and Uswatte (1998) for stroke patients first demonstrated in animal experiments and successfully adapted to clinical use. Constraint-induced therapy (CIT), uses a protocol aimed at increasing functional use of the more impaired upper extremity of stroke survivors with hemiparesis (Taub, Crago, Uswatte, 1998; Reiss, Wolf, Hammel, McLeod, & Williams, 2012).

Constraint-Induced Therapy in Stroke Rehabilitation

Taub, Crago, and Uswatte (1998) postulated that stoke survivors with unilateral upper extremity weakness may preferentially use the non-affected side while avoiding the use of the affected side, resulting in a "learned nonuse" phenomenon, first observed in animal experiments with monkeys (p. 55). Constraint-induced therapy (CIT) was proposed by Taub and his colleagues (1998) to overcome learned non-use by restraining the use of the non-affected arm, while engaging the patient in functional activities with the affected arm as will be further explained below. Constraint-induced movement therapy (CIT) is a method of treatment that involves restraint of the unaffected limb for up to 90% of waking hours, while forcing use of the affected limb, and by engaging it in shaping and intensive and repetitive task training 6 hours per day for two weeks (Nilsen et al., 2015; Taub et al., 1998). Studies have demonstrated significant improvement in arm motor function following the use of CIT (Wolf et al, 2006, Nilsen et al., 2015). The therapeutic effect of CIT is attributed to its induction of use-dependent cortical reorganization based on a theory of brain plasticity (Morris, Taub, & Mark, 2006; Sterr & Saunders, 2006).

Theoretical Basis of Constraint-induced Movement Therapy

The theoretical basis for constraint-induced therapy (CIT) is based on advances in neuroscience and behavioral psychology research involving the use of "operant conditioning techniques to change the arm-use behavior of monkeys from whose forelimbs somatic sensation had been surgically abolished" (Taub, Crago, & Uswatte, 1998). The monkeys stopped using the deafferented arm in the experiments, but could be trained to use the arm by immobilizing the intact arm for days, and training the affected arm (Miltner et al., 1999). Taub and colleagues (1998) explained the loss of motor function of the deafferented arm as a result of a learned behavior they aptly termed "learned nonuse" as a result of loss of sensory feedback, resulting in a decrease in functional use of the affected arm and developed a hypothesis that the same principles would apply in human beings with unilateral deafferentation following a stroke with hemiparesis. Taub, Crago, and Uswatte (1999) postulated that stoke survivors with unilateral upper extremity weakness may preferentially use the non-affected side while avoiding the use of the affected side, resulting in a “learned nonuse” phenomenon, first observed in animal experiments with monkeys (p. 55). Constraint-induced therapy (CIT) was proposed by Taub and his colleagues (1998) to overcome learned non-use by restraining the use of the non-affected arm, while engaging the patient in functional activities with the affected arm, thus inducing cortical reorganization based on a theory of brain plasticity (Miltner, Bauder, Sommer, Dettmers, & Taub, 1998; Shi, Tian, Yang, & Zhao, 2001; Page, Sisto, Levine, Johnston, & Hughes, 2001). Constraint-induced movement therapy (CIT) is a method of training that involves restraint of the unaffected limb for up to 90% of waking hours, forcing use of the affected limb by engaging it in activities 6 hours per day for two weeks (Page et al., 2001; Wolf & Nilsen, 2015).

Training protocols for the affected limb has evolved into repetitive adaptive task practice or shaping performed under the clinical supervision of therapist. Shaping is performed using blocks of a specific functional task, broken down into successive manageable components addressing components of the task that the patient is unable to complete using the affected arm (Reiss et al., 2012; Taub, Crago, & Uswatte, 1998). Shaping is conducted using operant conditioning strategies in which the therapist provides feedback to the patient, motivating the patient to use the affected limb in repetitive activities. The training, exercise, together with the forced use of the affected arm for long periods results in restoration based on the theory of brain neuroplasticity induced by “use-dependent increase in cortical reorganization” of the areas of the brain that control most affected limb (Reiss et al., 2012). Evidence for this is found in the study by Liepert and colleagues (2000), who used Transcranial Magnetic Stimulation to demonstrate a significant increase in the cortical hand representation in the affected hemisphere post constraint-induced therapy, an indication that the intervention produced a trend toward normalization of cortical representation. A 12-day period of CIT resulted in significantly increased area of cortical representation in the area of the affected cerebral hemisphere innervating the affected hand muscle, and corresponded to a greatly improved motor performance of the paretic limb (Liepert et al., 2000).

Elements of Constraint-induced Therapy

Although the constraint-induced therapy (CIT) protocol has undergone many modifications over the three decades of its use, the most commonly used protocols maintain three main elements that were present in the original protocol as described by Taub, Crago, and Uswatte (1998). These include repetitive task-oriented training of the affected upper extremity, constraining use of the more affected upper extremity, and adherence-enhancing behavioral strategies.

Repetitive task-oriented activities. In the original or signature CIT protocol, participants received 6 hours a day on weekdays of individualized training using functional task activities under the supervision of a therapist for a total of 2 weeks (Morris, Taub, & Mark, 2006). The training may consist of shaping using the principles of structured behavioral training as already described, or less structured task practice consisting of functionally based activities (Morris et al. 2006; Taub, Crago, & Uswatte, 1998). The duration of the supervised practice session have been reduced in modified constraint-induced treatment (mCIT) protocols with a wide variation observed in a systematic review and meta-analysis involving randomized controlled trials (RCTs) comparing mCIT with traditional rehabilitation (TR) by Shi, Tian, Yang, and Zhao (2011). The duration of the practice sessions ranged from 30 minutes/day for 3 days/week in 4 RCTs 1 hour/day for 3 days/week in 2 RCTs, 2 hours/day in 5 RCTs, and 2 hours/day for 5 days/week in 2 RCTs (Shi et al., 2011). This systematic review provided fairly strong evidence of the effectiveness of mCIT in reducing the level of disability, and improving the ability to use the paretic arm compared to TR. (Shi et al., 2011).

Constraining use of the more affected upper extremity. The original CIT protocol in incorporated the use of a restraint on the less affected upper extremity in the form of a sling (Morris, Taub, & Mark, 2006; Taub, Crago, & Uswatte, 1998). The form of restraint has since evolved to the use of a protective safety mitt which as explained by Morris and colleagues (2006) prevents the use of less affected hand while allowing the extension of that upper extremity for protection in case of a fall. The protective safety mitt appears to be the preferred method of restraint in most modified constraint-induced therapy research studies (Page, Sisto, Levine, Johnson, and Hughes, 2001; Nijland, Wegen, Krogt, Bakker, Buma, Klomp, Kordelaar, and Kwakkei, 2013). Participants wore the constraint for 90% of the hours spent awake for 14 days in the original CIT protocol (Taub, Uswatte, King, Morris, Crago, & Chatterjee, 2006). Modified constraint-induced therapy (mCIT) has been developed in which participants spend 5 hours each day with restraint applied to the affected upper extremity (Page, Levine, & Leonard, 2005).

Adherence-enhancing behavioral strategies. The third component of the original CIT protocol is the so-called “transfer package” which refers to techniques the authors developed to enhance patient engagement, participation, and accountability adhering to the requirements of the intervention protocol (Morris, Taub, & Mark, 2006). These were especially important in the context of the outpatient setting in which almost all these studies were conducted, and required patients to wear restraints on their less affected extremity for almost the whole day, while using their affected upper extremity for daily activities. The discipline and commitment in meeting their needs using a functionally impaired upper extremity, away from the supervision of a therapist must have been very demanding on patients.. Such measures include monitoring, problem-solving, and behavioral contracting (Morris et al., 2006). Participants were required to maintain a record of their activities and the duration of each activity to be reviewed by the therapist to encourage consistency and compliance. Problem solving may be addressed by teaching participants how to identify obstacles that may hinder their adherence to the treatment program, and how to overcome those obstacles through practical solutions. In addition, participants may be required to sign a formal contract to document their commitment to perform activities they have mutually agreed to with the therapist, during their hours wearing the restraint (Taub, Crago, & Uswatte, 1998; Morris et al., 2006).

Outcome Measures in Modified Constraint-Induced Therapy Research

The development of constraint-induced therapy (CIT) and modified constraint-induced therapy (mCIT) created a need to develop new outcome measures so as to adequately measure "functional activity in the life situation" as the most important outcome measure for the new intervention (Taub, Crago, & Uswatte, 1998). These included the Motor Activity Log (MAL; Taub et al., 1998) and the Actual Amount of Use Test (AAUT; Taub et al., 1998), the Wolf Motor Function Test (WFMT; Taub et al., 1998; Wolf, Lecraw, Barton, & Jann, 1989), the Action Research Arm Test (ARA; Page, Levine, Leonard, 2005), the Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA; Fugl-Meyer, Jaasko, Leyman, Olsson, & Steglind, 1975; Page, Levine, Leonard, 2005). Studies demonstrating the reliability and validity of these instruments have resulted in their near universal adoption as the standard outcome measures in CIT research and practice (Uswatte, Taub, Morris, Light, & Thompson, 2006; Wolf, Catlin, Ellis, Morgan, & Piacentino, 2001; Morris, Uswatte, Crago, Cook III, & Taub, 2001; Duncan, Propst, & Nelson, 1983; Hsieh et al., 2009).

Development of Modified Constraint-Induced Therapy

Physical deconditioning due to the stroke and co-morbid conditions typically associated with the stroke patient population including impaired cardiovascular fitness, gait deficit, and the impact of aging have been mentioned as some of the reasons why these patients may be unable to participate in a traditional CIT stroke rehabilitation program (Page, Sisto, Levine, & McGrath, 2004). Concern about compliance with long duration of restriction of the less affected upper extremity to 90% of waking hours, and the intensity of the shaping therapy lasting up to six hours daily for two weeks led Page, Sisto, Levine, Johnston, and Hughes (2001), working with others in their lab to describe a modified constraint-induced therapy approach (mCIT). The CIT modified protocol proposed by Page et al. (2001) addresses these concerns in order to improve the feasibility and the likelihood of compliance in the clinic. The amount of time in which the non-affected limb is restrained, and the activity sessions for the affected limb are substantially decreased and /or distributed over a longer period of time (Page et al., 2001). In a description of their mCIT protocol, Page, Levine, and Leonard (2005) combined ½ hour therapy sessions three days a week for 10 weeks of functional practice sessions, with restriction of the unaffected limb for five hours each day for five days each week for 10 weeks.

Effectiveness of Modified Constraint-Induced Therapy and Role in Stroke Rehabilitation

Several studies including those of Page, Sisto, Levine, Johnston, and Hughes (2001) and Siebers, Oberg, and Skargren (2010) have shown that modified constraint induced therapy (mCIT) is an efficacious method of improving function and use of the affected arm of patients with hemiparesis following chronic stroke. The efficacy of mCIT in increasing affected arm use and function has been demonstrated mostly in the outpatient clinics on patients with subacute (Page, Sisto, Johnson, Levine, & Hughes 2002) and chronic stroke (Page, Sisto, Levine & McGrath, 2004; Page, Levine, Leonard, Szaflarski, & Kissela, 2008). Preliminary and pilot studies demonstrating the feasibility and efficacy of mCIT in acute stroke rehabilitation have been reported by Dromerick, Edward, and Hahn (2000) and Page, Levine, and Leonard (2005).

However, constraint-induced therapy (CIT) and modified constraint-induced therapy (mCIT) are still not widely used in inpatient rehabilitation hospitals, which are the setting most patients with acute stroke are discharged to. A study by Latham et al. (2006) noted that that CIT was the approach or type of occupational therapy intervention used in only 2.7% of all interventions in a study of rehabilitation techniques for clients with stroke in six rehabilitation hospitals. The study included 954 patients who had had a recent stroke (within 1 year of admission) as a reason for admission, and had had no interruption in rehabilitation services of greater than 30 days (Latham et al., 2006). In addition, Smallfield and Karges (2009) have noted from their study findings that occupational therapy intervention in an inpatient rehabilitation hospital used slightly more preparatory activities than occupation-based activities.

In order to demonstrate the feasibility and efficacy of mCIT in patients with acute stroke in inpatient rehabilitation hospitals, studies have been published in recent years demonstrating the efficacy of mCIT for inpatient rehabilitation of patients with acute and subacute stroke with protocols lasting from 2-4 weeks in studies in China, Europe, and India, and the United States (Wang, Zhao, Zhu, Li, & Meng, 2011; El-Helow et al., 2015; Singh & Pradhan, 2013; Dromerick et al., 2009; Dromerick, Edward, and Hahn, 2000; Page, Levine, and Leonard, 2005). Nijland, Wegen, Krogt, Bakker, Buma, Klomp, Kordelaar, and Kwakkei (2013) have described in detail a protocol for early mCIT in patients with acute stroke. This study provided the most detailed description of mCIT protocol utilized in evidence-based research. In their protocol, repetitive task training is applied for one hour per working day, and the patient wears a mitt on the less affected hand for a minimum of 3 hours per day for 3 consecutive weeks (Nijland et al., 2013). The key feature of this protocol is the provision of homework to patients at the end of each training session with the aim of encouraging them to exercise the more affected limb during the 3 hours in which the restraint is worn (Nijland, 2013). This descriptive study is an important resource for researchers developing mCIT protocols, and practicing therapists seeking to implement mCIT evidence in real world clinical practice (Nijland et al., 2013).

Settings for Stroke Rehabilitation

Stroke care in the United States starts in acute care hospitals where patients admitted with acute stroke receive an evaluation, and diagnostic tests for the first few days (Krakauer, Carmichael, Dale, Corbett, & Wittenberg, 2012). Once medically stable, they are discharged to a variety of settings ranging from home with no therapy, home therapy program, skilled nursing facilities, and inpatient hospitals (Krakauer et al., 2012; Wolf & Nilsen, 2015). For those in need an inpatient rehabilitation hospital is the recommended setting for patients who are medically stable and possess the ability to tolerate at least 3 hours of multidisciplinary rehabilitation program including formal physical, occupational, and speech therapy per day for 5-7 days per week (Krakauer et al., 2012; Management of Stroke Rehabilitation Working Group, 2010; Wolf & Nilsen, 2015). Stroke survivors who are unable to tolerate the intensity of the program in an inpatient rehabilitation hospital, or require 24-hour care or skilled medical care are usually referred to a subacute rehabilitation facility. Upon discharge from inpatient rehabilitation hospitals and, subacute rehabilitation facilities, clients may receive further service in community settings as outpatient programs or in-home services (Krakauer et al., 2012; Management of

Stroke Rehabilitation Working Group, 2010; Wolf & Nilsen, 2015). As recommended in the Practice Guidelines of the American Occupational Therapy Association, occupational therapy services at the rehabilitation phase of recovery which occur in inpatient rehabilitation hospitals should focus on restoration of and compensation for performance deficits affecting occupational performance, and maximizing independence in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) in preparation for the patient's return to community living (Wolf & Nilsen, 2015).

Conclusion

Although demonstrating great promise, with reasonably strong evidence of feasibility and efficacy, published research on constraint-induced therapy (CIT) and modified constraint-induced therapy (mCIT) have been hampered by methodological limitations, mostly due to small sample sizes. Other limitations include the use of subjective outcome measures, including self-report measures, like the Motor Activity Log (MAL), and observer-initiated measures like the Fugl-Meyer (FM) assessment, and the Action Research Arm (ARA) test as clearly stated by Page et al (2005). Some of the studies do not include long-term follow up to assess the long-term effects of this approach in many of the studies (El-Helow et al., 2005; Dromerick et al., 2009). In spite of the limitations, the available evidence has clearly demonstrated the efficacy and feasibility of mCIT in the rehabilitation of patients with chronic, subacute, and acute stroke. The proposed study will focus on the implementation of mCIT in the upper extremity rehabilitation of patients with acute stoke in an inpatient rehabilitation hospital. It makes sense to explore its implementation in routine stroke rehabilitation in an inpatient rehabilitation hospital, which is the routine disposition setting for most acute stroke patients. Since mCIT has been demonstrated to reverse the effects of learned nonuse (Page et al, 2005), doesn't it make more sense to apply it early in the acute stage of an inpatient rehabilitation hospital in the first instance to prevent

Section 3: Methods

Project Design:

This research is designed to demonstrate the feasibility and efficacy of the implementation of an evidence-based approach in routine upper extremity stroke rehabilitation of patients with acute strokes in an inpatient rehabilitation hospital, by comparing the impact of modified constraint-induced therapy (mCIT) to traditional stroke rehabilitation in that setting. This will be achieved through an experimental study design to test the hypothesis that mCIT will lead to greater motor recovery of the affected arm, an increase in number and quality of arm use, and improvement in occupational performance compared to traditional stroke rehabilitation (TR) of patients with acute stroke in an inpatient rehabilitation hospital, controlling for the dose of intervention used. The study will use a multiple baseline, randomized, controlled pretest-posttest design. The study design will use a dose-matched control intervention (TR) for comparison with mCIT in designing the two intervention protocols for the study (Stinear, Ackerley & Byblow, 2013). This design involves random assignment of the participants to two groups to receive either mCIT: Group A, or traditional rehabilitation (TR): Group B. Each group will be administered both a pretest occupational profile (American Occupational Therapy Association, 2014 and outcomes namely the Canadian Occupational Performance Measure (COPM), the Fugl-Meyer Assessment (FMA), the Wolf Motor Function Test (WMFT), and the Motor Activity Log (MAL). It is a between-subject design using the two treatment variables (mCIT and TR as independent variables), and the simultaneous effects of these treatment variables on outcomes (dependent variables). A single occupational therapist, the principal investigator who will be trained to acquire proficiency, will administer all the pretest and posttest instruments including the COPM, FMA, WFMT, and the MAL. The testing therapist will be blinded to the group assignment of the subjects in the pre- and post- test.

Description of Project Setting

HealthSouth Rehabilitation Hospital in Kingsport, Tennessee is a 50-bed inpatient rehabilitation hospital that provides comprehensive rehabilitation to diagnoses such as orthopedic, neurological, cardiac, and pulmonary, and specialized inpatient programs for stroke, brain injury and trauma. It is part of a national network of rehabilitation hospitals owned by HealthSouth, one of the nation's largest providers of post-acute care healthcare services. The key community partners of the HealthSouth Rehabilitation Hospital, Kingsport include Holsten Valley Medical Center in Kingsport, Indian Path Medical Center in Kingsport, and Johnson City Medical Center in nearby Johnson City which are its most important referral hospitals from the two health systems in the Northeast Tennessee community. Other community partners include a large number of community nursing homes operating skilled nursing facilities, outpatient rehabilitation centers, and home health organizations. Their Mission statement is to be the healthcare company of choice for patients, employees, physicians and shareholders by providing high quality care in the communities.

HealthSouth Hospital, Kingsport serves Sulivan County, Tennessee with population of 157, 419 of which, 94% are non-Hispanic Whites, 2.3% are African Americans, and 1.6% Hispanics (County Health Rankings & Roadmaps, 2013). The hospital also attracts patients from nearby Washington County and Bristol in Tennessee, and adjacent counties in Southwest Virginia. Tennessee ranks 42 of 50 states in national health ranking in overall health outcomes, ranking among the highest in adult obesity (40), physical inactivity (45), infant mortality (47), cardiovascular deaths (44), cancer deaths (45), and premature deaths (43) (United Health Foundation, 2013).

The leadership team in HealthSouth Kingsport has six directors working under a chief executive officer. The director of therapy services is a physical therapist and oversees the four therapy departments including physical therapy, occupational therapy, speech therapy, and respiratory therapy, each with their own supervisor. The major programs and services provided include specialized rehabilitation services including amputee, arthritis, balance and vestibular rehabilitation, bowel and bladder training, brain injury, hip fracture, joint replacement, neurological disorders, Parkinson’s disease, strokes, spasticity management, spinal injury, multiple trauma and others.

Early rehabilitation of individuals after a stroke occurs in inpatient rehabilitation hospitals. There is a strong need to implement an evidence-based approach for upper extremities rehabilitation of stroke patients with interventions that target the client’s preferred outcomes in order to make stroke rehabilitation more occupation-based, evidence-based, client-centered and therefore increase the likelihood of client engagement, participation and satisfaction with therapy (Baum & Law, 1997). Conducting this study on patients with acute stroke in an inpatient rehabilitation hospital will also enable research and clinical practice to target stoke rehabilitation to the early period (first 30 days) after stroke which has been identified as a period of “heightened plasticity” of the brain, and a critical time period for initiation of treatment (Krakauer, Carmichael, Corbett, & Wittenberg, 2012, p 923). This setting was chosen in order to align the evidence of effectiveness of the intervention to the timing of stroke rehabilitation in routine occupational therapy practice. Much of the evidence of feasibility and effectiveness of constraint-induced therapy (CIT), and modified constraint-induced therapy (mCIT) have been obtained for chronic, and subacute strokes in outpatient settings, whereas in the real world, stroke rehabilitation routinely begins in inpatient rehabilitation hospitals with acute strokes. As stated by Stinear, Ackerley, and Byblow (2013), such misalignment between timing of interventions in research studies and what obtains in the real world may account for a significant limitation in the translation of research evidence to clinical practice.

Identification of Participants:

The participants in this study will be a convenience sample of all patients with acute stroke who are admitted to the inpatient rehabilitation hospital during the study period. To be included in the study, a client must have has an ischemic stroke within two weeks prior to enrollment into the study. In addition, participants will demonstrate the following inclusion criteria including the ability to actively extend at least 5 degrees at the metacarpophalangeal and interphalangeal joints and 10 degrees at the wrist, a score of ≥ 70 on the Modified Mini-Mental State Exam, age ≥ 18 ≤ 95, no excessive spasticity, as defined by a score ≤ 3 on the Modified Ashworth Spasticity Scale, and no excessive pain in the affected upper limb, measured by ≤ 4 on a 10-point visual analog scale, and not participating in any other experimental rehabilitation or drug study, and more affected upper limb nonuse defined as an amount of use score of < 2.5 on the Motor Activity Log (Page, Sisto, & Levine, 2002; Page, Sisto, Johnston, Levine, & Hughes, 2002; Page, Levine, & Leonard, 2005). The exclusion criteria will include those with stoke longer than 14 days prior to study enrollment, excessive spasticity as defined by a score > 3 on the Modified Ashworth Spasticity Scale, excessive pain in the affected upper limb measured by a score of > 4 on a 10-point visual analog scale, participants aged < 18, pregnant, or participating in any other experimental rehabilitation study or drug studies. A total of 10-12 participants will be enrolled for the study, and these will be randomized to the two groups.

The principal investigator will be notified by the admissions liaison that a patient with acute stroke has been accepted for admission to the inpatient rehabilitation hospital and will conduct a preliminary screening based on demographic and clinical data provided. She will follow up with a formal screening using the inclusion criteria. The informed consent will be obtained according to the mandate of the Eastern Kentucky University Institutional Review Board for participants who meet the inclusion criteria and have indicated an interest in taking part in the study.

Project Methods

After screening and informed consent, the enrolment data of the participant accepted for the study will be sent in a designated folder to a designated staff trained to complete the enrolment by randomly assigning each enrollee to one of two groups, A or B, representing participants designated for modified constraint-induced therapy (mCIT), or traditional rehabilitation (TR). Random allocation of participants will be performed through computer software generated random sequence. The allocation will be concealed from the researcher, the participant, and all members of the research team, and will only be revealed to the treating therapist by the enrolling staff after pretest measures have been administered.

Instruments

The principal investigator will administer the outcome measures on all study participants prior to intervention and at the end of the intervention (pre- and post-test). This will prevent potential variation in the assessments. The assessments include the Canadian Occupational

Performance Measure (COPM), the Fugl-Meyer Assessment (FMA), the Wolf Motor Function Test (WMFT), and the Motor Activity Log (MAL). The principal investigator will be blinded to the pre- or post-test treatment status of the patient.

The Canadian Occupational Performance Measure (COPM, 2015). The COPM is an individualized, client-centered outcome measure for identification and evaluation of self-perceived occupational performance problems, establishment of treatment goals and assessing changes in perceived performance and satisfaction with occupational performance over time (Law et al., 1990; Cup, Scholte op Reimer, Thijsen, & van Kuy-Minis, 2003; Eyssen et al., 2011). The method of administration will involve asking participants to identify occupational performance problems in the areas of self-care, productivity and leisure, then rating the importance of each activity and rating their performance and satisfaction with each activity. Several studies have demonstrated acceptable test-retest and inter-rater reliability and acceptable validity of the COPM, and its usefulness as a measure of change in occupational performance and satisfaction from the initial evaluation and identification of the specific needs of the client and setting of treatment goals, thus enabling meaningful goal directed interventions (Cup et al. 2003; Eyssen et al., 2011; Phipps & Richardson, 2007).

The Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA). The FMA is a quantitative measure of motor recovery, balance, sensation, coordination, and speed following stroke (Fugl-Meyer, Jaasko, Leyman, Olsson, & Steglind, 1975). The upper extremity section of the FMA that will be used for this study is a 66-point assessment of several impairments using a 3-point ordinal scale ranging from 0 (cannot perform, and 1 (can perform partially), to 2 (can perform fully). The participant is tested on each item by giving a verbal instruction, and carries out the movement with the less affected upper extremity, and then attempts the same movement with the affected extremity. Movements are tested from proximal to distal with the more difficult movements performed in the latter stage of the test. Studies have shown that the FMA has high test-retest and inter-rater reliability (Duncan, Propst, & Nelson, 1983; Hsieh et al., 2009). The FMA also demonstrated a large degree of responsiveness, and good construct and predictive validity properties and is a relatively sound outcome measure of motor function after stroke compared to the Action Research Arm test (ARAT) and the Wolf Motor Function Test (Hsieh et al., 2009).

The Wolf Motor Function Test (WMFT). The WMFT was originally conceptualized to examine the effects of forced use or constraint-induced therapy (CIT) on motor function of survivors of strokes and traumatic brain injury (Wolf, Lecraw, Barton, & Jann, 1989). It has since been modified to serve as a reliable outcome measure in CIT research on stroke with all degrees of functioning demonstrating high inter-rater reliability, internal consistency, test-retest reliability, construct validity, and criterion validity, and adequate stability (Wolf, Catlin, Ellis, Morgan, & Piacentino, 2001; Morris, Uswatte, Crago, Cook III, & Taub, 2001). Wolf, McJunkin, Swanson, and Weiss (2006) provided a pilot normative database to serve as reference points to describe patients, set goals, and evaluate treatments. The revised protocol as described by Page, Sisto, Levine, Johnston, and Hughes (2002) will be used for this study. The designated therapist (the principal investigator) will obtain a measure of the patient's ability to perform 19 simple limb movements and tasks with the affected upper extremity. Two of the items measure strength, and 17 items are timed and scored.

Motor Activity Log (MAL) and Daily Dairy. The MAL is a semi-structured interview measuring how stroke patients use their affected limb for 30 important activities of daily living (ADLs) during the period under review will be used for this study (Morris, Taub, & Mark, 2006;

Page, Sisto, Levine, Johnston, & Hughes, 2002). During the MAL interview, the participants will be asked to independently rate how much and how well they have used the affected arm the designated activities during the past week. The participant will rate how much they are using their affected arm for each item on a 6-point scale for Amount of Use (AOU), and how well they are using their affected arm on a 6-point scale for Quality of Movement (QOM). Tasks include classic ADLs, such as brushing teeth, buttoning a shirt/blouse, and eating with a fork or spoon. Data analysis from a multisite, randomized, controlled trial of early and delayed constraint-induced therapy showed that the MAL exhibited reliability and good convergent validity (Uswatte, Taub, Morris, Light, & Thompson, 2006). In addition to the MAL interview of the activities for the week preceding the beginning of the study, and the MAL interview of activities during the week at the end of the interventions, the participants list their activities outside the lab during the period in which they are wearing the restraint, and report if they are using their more affected upper extremities particularly on those activities listed in the behavioral contract (Morris, Taub, & Mark, 2006). The treating therapist will conduct a daily review of the of the dairy in order to “heighten participants’ awareness of their use of the more affected upper extremity and emphasize adherence to the behavioral contract and the patients’ accountability for their own improvement” (Morris, Taub, & Mark, 2006, p. 262).

Interventions

Each participant will be provided individualized 1 hour occupational therapy session, 5 times/week for 2 weeks using either the modified constraint-induced therapy (mCIT) protocol, or the traditional rehabilitation (TR) protocol designed for this study based on his/her randomized group assignment. The same therapist, who alone will be informed of the treatment group assignment, will provide each participant’s entire treatment. In addition, all participants assigned to mCIT will be required to wear a restraint on the less affected upper extremity 5 hours each weekday at a time of frequent use using a polystyrene-filled mitt, while they perform daily activities using the affected upper extremity. They will be required to keep an activity log to record all their activities during the 5 hours of restraint, and the restraint device use time.

Modified Constraint-Induced Therapy (mCIT). Each participant assigned to mCIT will participate in individualized 1-hour occupational therapy session, 5 times/week for 2 weeks, administered to the affected upper extremity by the same therapist. The therapy session will be spent on shaping techniques and include challenging activities targeting deficient components of 2-3 activities chosen by the participant with help from their therapist, e.g. writing, using a fork and spoon, brushing teeth, combing hair (Page & Levine, 2007). “Shaping” is defined as an operant conditioning training method in which a desired behavioral or motor objective is “approached in small steps by successive approximations” (Morris, Taub, & Mark, 2006, p. 259). The approach requires training in the desired behavior in small incremental steps of increasing difficulty, while rewarding the participant with enthusiastic approval for improvement, but never blaming him/her for failure (Taub et al, 1998; Page, Sisto, Johnston, Levine, & Hughes, 2002; Morris, Taub, & Mark, 2006). The movements responsible for the functional tasks selected as most important by the participant is broken into the smallest measurable elements by the therapist (Page & Levine, 2007). The therapist will identify the deficient component for a particular participant during initial evaluation and will direct and encourage the participant to practice that component repeatedly during the treatment session. For example, eating with a spoon may be broken down into reaching for the item, grasping it, scooping the food item, and bring it to the mouth. The individual components are progressively mastered, then combined until the entire movement can be performed. During the training process, each element will be timed to document the smallest improvement in performance. An important component of shaping is for the interventionist to provide verbal reinforcement promptly when performance improvement is made. Also, when 3 or more negative unsuccessful attempts are made, the therapist should provide reinforcement in the form of encouraging comments but never negative or discouraging (Page & Levine, 2007). Other elements include the use of modeling or coaching through use of cues or prompts (Morris, Taub, & Mark, 2006; Page & Levine, 2007). As stated by Morris, Taub, & Mark (2006), tasks to be used will emphasize movements in need of improvement, and at the upper range that can be accomplished by the participant, yet avoiding excessive effort that could demotivate the participant. Participants will receive 1 hours of individual training of the affected extremity daily for 5 days a week for 2 weeks. Each session may be divided into two 30-minute sessions or three 20-minute sessions depending on the subject's ability to sustain training. The mCIT protocol also includes a requirement for the clients' less affected upper extremity to be restrained for 5 hours each weekday at a time of frequent use using a polystyrene-filled mitt, while they perform daily activities using the affected upper extremity, keep a detailed log of all activities and restraint time use. The treating therapist will review this record daily and document the individual participant's training activities and progress. Prior to commencing the study, each participant will sign a behavioral contract detailing the agreed upon activities they would carryout when wearing the restraint.

Traditional Rehabilitation (TR). Each participant assigned to TR will participate in individualized 1-hour occupational therapy session, 5 times/week for 2 weeks, administered by the same therapist similar to the traditional occupational therapy offered to patients with acute stroke at HealthSouth Rehabilitation Hospital, Kingsport. The individualized occupational therapy sessions will consist of compensatory techniques for activities of daily living (ADL), range of motion, strengthening, and traditional positioning for the affected upper extremity. This will consist of a combination of ADLs, weight bearing, guarding functional reach, and electrical stimulation. The exact treatment prescription for each patient will be tailored to each patient's clinical and functional assessment. No restraint will be used and participants will be allowed to use either upper extremity for their daily activities.

Data analysis

Data analysis will be performed using Statview software (SAS Institute Inc., Cary, NC). Descriptive statistics will be used to summarize the demographic information of the participants and the outcome measures at baseline and after 2 weeks of therapy for the two groups, modified constraint-induced therapy (mCIT) and traditional rehabilitation (TR). These include a measure of the participants' occupational performance using the COPM, the motor recovery using the FMA, motor function using the WMFT, and number and quality of arm use according to the MAL. A comparison between treatment groups with respect to demographics, and the clinical measures of outcome will be performed using the Student's t-test. Paired t-test statistics will be used to analyze the difference within each group before and after intervention in the COPM, FMA, WMFT, and MAL. The significance level will be set at $\alpha = .05$ for all analysis.

Ethical Considerations

The study proposal will undergo an institutional review board and the HealthSouth Corporate Research Review Committee application process before the study commences. Informed consent will be obtained from all participants before enrolment. All participants will benefit from stroke rehabilitation in the process of their participation. Fidelity to confidentiality of patient interviews, medical records and all research documents will be maintained.

Documentation of agreements regarding authorship of any publication resulting from study will be completed before commencement of the study. Meticulous efforts will be made to keep the pre-test and post-test assessor blind to the treatment group assignment throughout the period of the study. The random allocation sequence generated from the computerized program will be kept in secure computer files password protected and known only to the enrolling staff, and a physical file kept under lock and key by the enrollee. The treating occupational therapists delivering the interventions will keep detailed documentation of the interventions delivered, and each participant's response to the intervention of each participant's response to intervention. Treatment data for each participant will be documented sheet kept by each treating therapist and entered into password –protected electronic data file.

Timeline of Project

The need assessment study for this project was completed in the fall of 2015. Project proposal and institutional review board application are being prepared for submission this term. A Principal Investigator's Disclosure Agreement has already been submitted to HealthSouth Corporate Research Committee. Pending approval from both entities, data collection will be implemented during the summer term of 2016 for a period of 8 weeks. The project report will be prepared and presented in the fall term of 2016.

Conclusion

Using this experimental approach, this study will provide evidence of improved outcomes following routine application of modified constraint-induced therapy (mCIT) in stroke rehabilitation in an inpatient rehabilitation hospital. It will serve as a pilot program for an evidence-based approach to stroke rehabilitation in inpatient rehabilitation hospitals.

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